

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,)
)
 Plaintiff,) Civil Action No. 1:10 cv-1376 TWP-DML
 v.)
)
 TEVA PARENTERAL MEDICINES, INC.,)
 APP PHARMACEUTICALS, LLC,)
 PLIVA HRVATSKA D.O.O.,)
 TEVA PHARMACEUTICALS USA, INC., and)
 BARR LABORATORIES, INC.,)
)
 Defendants.)

CASE MANAGEMENT PLAN

I. Parties and Representatives

A. Plaintiff: Eli Lilly and Company (“Lilly”)

Defendants: Teva Parenteral Medicines, Inc. (“Teva”)
APP Pharmaceuticals, LLC (“APP”)
Pliva Hrvatska D.O.O (“Pliva”)
Teva Pharmaceuticals USA, Inc. (“Teva USA”)
Barr Laboratories, Inc (“Barr”)

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Counsel shall promptly file a notice if there is any change in this information.

II. Synopsis of Case

A. **Plaintiff's Statement.** This case is a Hatch-Waxman patent infringement action, arising out of the filing of Abbreviated New Drug Applications ("ANDAs") to make and sell generic copies of a drug product known as ALIMTA®. Lilly sells

ALIMTA® (pemetrexed disodium), a chemotherapy drug used for the treatment of various types of cancer.

U.S. Patent No. 7,772,209 (“the ’209 patent”) covers a method of administering ALIMTA® to a patient that also involves the administration of folic acid and vitamin B₁₂. Lilly is the assignee of the ’209 patent.

Defendants have filed ANDAs with the FDA for the purpose of obtaining approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to manufacture and sell generic copies of ALIMTA® (Defendants’ “ANDA products”) prior to the expiration of the ’209 patent. The filing of the ANDAs constitutes infringement of the ’209 patent. The use of Defendants’ ANDA products in accordance with their proposed labeling would infringe the ’209 patent and Defendants will induce and contribute to that infringement.

As set forth in the Plaintiff’s complaint, Plaintiff seeks, *inter alia*, an order that the effective date of any FDA approval for Defendants’ ANDA products be not earlier than the expiration date of the ’209 patent, including any extensions or additional periods of exclusivity, injunctive relief enjoining Defendants and those acting in concert with them from infringing, inducing the infringement of, or contributing to the infringement of, the ’209 patent, and a declaration that making, using, selling, offering for sale, marketing, distributing, or importing any of Defendants’ ANDA products will infringe, actively induce infringement of, and contribute to the infringement of by others of the ’209 patent.

The court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

B. **Defendants’ Statement.** As set forth in Defendants’ Answers, the claims of the ’209 patent are invalid under 35 U.S.C. §§ 101 *et seq.* and for obviousness-type double patenting. Making, using, selling, offering for sale, marketing, distributing and/or importing of Defendants’ ANDA products in the United States do not infringe the claims of the ’209 patent. Furthermore, Defendants will not induce infringement of or contribute to the infringement by others of the ’209 patent. As such, Defendants should be allowed to market their ANDA products before the expiration date of the ’209 patent.

Defendants seek an order, *inter alia*, dismissing the Complaint, with prejudice, denying Plaintiff the relief requested in the Complaint and any relief whatsoever, and declaring that the ’209 patent is invalid and not infringed by Defendants’ ANDA products.

III. Pretrial Pleadings and Disclosures

A. The parties shall serve their Fed. R. Civ. P. 26 initial disclosures on or before **April 11, 2011.**

- B. All motions for leave to amend the pleadings and/or to join additional parties shall be filed on or before **May 12, 2011**.
- C. Plaintiff shall serve Disclosure of Asserted Claims and Preliminary Infringement Contentions on or before **May 12, 2011** which shall contain the following information:
 - 1. Each claim of each patent in suit that is allegedly infringed by each opposing party;
 - 2. Separately for each asserted claim, each accused apparatus, product, device, process, method, act, or other instrumentality (“Accused Instrumentality”) of each opposing party of which the party is aware. This identification shall be as specific as possible. Each product, device, and apparatus must be identified by name or model number, if known. Each method or process must be identified by name, if known, or by any product, device, or apparatus which, when used, allegedly results in the practice of the claimed method or process;
 - 3. A Plaintiff’s Claim Chart identifying specifically where each element of each asserted claim is found within each Accused Instrumentality, including for each element that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function;
 - 4. Whether each element of each asserted claim is claimed to be literally present or present under the doctrine of equivalents in the Accused Instrumentality;
 - 5. For any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled; and
 - 6. If a party claiming patent infringement wishes to preserve the right to rely, for any purpose, on the assertion that its own apparatus, product, device, process, method, act, or other instrumentality practices the claimed invention, the party must identify, separately for each asserted claim, each such apparatus, product, device, process, method, act, or other instrumentality that incorporates or reflects that particular claim.

With the “Disclosure of Asserted Claims and Preliminary Infringement Contentions,” the party claiming patent infringement must produce to each opposing party or make available for inspection and copying:

- a. Documents (e.g., contracts, purchase orders, invoices, advertisements, marketing materials, offer letters, beta site testing agreements, and third party or joint development agreements) sufficient to evidence each discussion with, disclosure to, or other

manner of providing to a third party, or sale of or offer to sell, the claimed invention prior to the date of application for the patent in suit. A party's production of a document as required herein shall not constitute an admission that such document evidences or is prior art under 35 U.S.C. § 102;

- b. All documents evidencing the conception, reduction to practice, design, and development of each claimed invention, which were created on or before the date of application for the patent in suit or the priority date; and
- c. A copy of the file history for each patent in suit.

The producing party shall separately identify by production number which documents correspond to each category.

D. Defendants shall serve Preliminary Invalidity Contentions on or before **June 27, 2011.**

Each party opposing a claim of patent infringement shall serve on all parties its "Preliminary Invalidity Contentions," which must contain the following information: (a) The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious. Each prior art patent shall be identified by its number, country of origin, and date of issue. Each prior art publication must be identified by its title, date of publication, and where feasible, author and publisher. Prior art under 35 U.S.C. § 102(b) shall be identified by specifying the item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known. Prior art under 35 U.S.C. § 102(f) shall be identified by providing the name of the person(s) from whom and the circumstances under which the invention or any part of it was derived. Prior art under 35 U.S.C. § 102(g) shall be identified by providing the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant(s); (b) Whether each item of prior art anticipates each asserted claim or renders it obvious. If a combination of items of prior art makes a claim obvious, each such combination, and the motivation to combine such items, must be identified; (c) A chart identifying where specifically in each alleged item of prior art each element of each asserted claim is found, including for each element that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and (d) Any grounds of invalidity based on indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims.

With the “Preliminary Invalidity Contentions,” the party opposing a claim of patent infringement must produce or make available for inspection and copying: (a) Source code, specifications, schematics, flow charts, artwork, formulas, and other documentation sufficient to show the operation of any aspects or elements of an Accused Instrumentality identified by the patent claimant in its Plaintiff’s Claim Chart; (b) A copy of each item of prior art identified which does not appear in the file history of the patent(s) at issue. To the extent any such item is not in English, an English translation of the portion(s) relied upon must be produced.

- E. The parties shall simultaneously exchange lists of claim terms, phrases, or clauses which they contend should be construed by the court and identify any claim element which they contend should be governed by 35 U.S.C 112(6) on or before **July 11, 2011**. The parties shall thereafter meet and confer for the purposes of finalizing these lists, narrowing or resolving differences, and facilitating the ultimate preparation of a Joint Claim Construction Statement.¹
- F. The parties shall disclose the name, address, and vita of each expert witness whom they intend to use in support of their *Markman* brief and/or call at the *Markman* hearing on or before **August 1, 2011**. If a party discloses an expert witness on this deadline, any party that did not identify an expert witness on this deadline may disclose the name, address and vita of an expert witness whom they intend to use in support of their *Markman* brief and/or call at the *Markman* hearing on or before **August 5, 2011**.
- G. On or before **August 1, 2011** the parties shall simultaneously exchange a preliminary proposed construction of each claim term, phrase, or clause which the parties collectively have identified for claim construction purposes. Each such “Preliminary Claim Construction” shall for each element which any party contends is governed by 35 U.S.C. § 112(6), identify the structure(s), act(s), or material(s) corresponding to that element. By the same date, the parties also shall provide a preliminary identification of extrinsic evidence, including without limitation, dictionary definitions, citation to learned treatises and prior art, and testimony of percipient or expert witnesses they contend support their respective claim constructions. The parties shall identify each such item of extrinsic evidence by production number or produce a copy of any such item not produced. With respect to any percipient witness, the parties shall also provide a brief description of the substance of that witness’ proposed testimony.
- H. Within **10 days** after service of the statements of preliminary claim construction, the parties shall meet and confer to discuss issues relating to claim construction. During this meeting, the parties shall confer for the purposes of narrowing or

¹ Should the parties determine on or about July 11, 2011 that no claim terms, phrases or clauses require construction, the parties agree to meet and confer in good faith to negotiate a proposal for the remainder of the schedule to be presented to the court in advance of the next case management conference.

resolving differences and facilitating the ultimate preparation of a Joint Claim Construction Statement.

- I. If Plaintiff identified a *Markman* expert, Plaintiff shall serve the expert report required by Fed. R. Civ. P. 26(a)(2)(B), on or before **September 9, 2011**.
- J. If Defendants identified a *Markman* expert, Defendants shall serve the expert report required by Fed. R. Civ. P. 26(a)(2)(B) within 30 days after Plaintiff serves its expert witness disclosure; or if none, Defendants shall make its expert disclosures on or before **October 10, 2011**.
- K. The parties shall file a Joint Claim Construction Statement on or before **October 17, 2011**, if a *Markman* expert is identified, or on or before **August 22, 2011**, if a *Markman* expert is not identified. The Joint Claim Construction Statement shall contain the following information: (a) the construction of those claims, terms, phrases, or clauses on which the parties agree; (b) each party's proposed construction of each disputed claim, term, phrase, or clause; (c) the anticipated length of time necessary for the *Markman* hearing; and (d) whether any party proposes to call one or more witnesses, including experts, at the *Markman* hearing, the identity of each such witness, and for each expert, a summary of each opinion to be offered in sufficient detail to permit a meaningful deposition of that expert.
- L. A settlement conference before the assigned magistrate judge or, if the parties prefer, private mediation, will be held approximately **10 days** after the parties file the Joint Claim Construction Statement.

M. *Markman* Briefing

Track 2

The Plaintiff shall file an opening *Markman* brief on or before **November 7, 2011**, if a *Markman* expert is identified, or on or before **September 9, 2011**, if a *Markman* expert is not identified. The Defendants shall file their *Markman* brief **20 days** later. The Plaintiff shall file a reply brief **10 days** later.

- N. The parties should anticipate that a *Markman* hearing will be held approximately **December 23, 2011**, if a *Markman* expert is identified, or **October 24, 2011**, if a *Markman* expert is not identified.
- O. Not later than **15 days after the court's *Markman* decision**, the court shall set a case management plan conference at which Phase II dates and trial date will be set.
- P. Each party opposing a claim of patent infringement that will rely on an opinion of counsel as part of a defense to a claim of willful infringement shall: (i) Produce the opinion(s) and any other documents relating to the opinion(s) as to which that

party agrees the attorney-client or work product protection has been waived; and
(ii) Serve a privilege log identifying any other documents, except those authored by counsel acting solely as trial counsel, relating to the subject matter of the opinion(s) which the party is withholding on the grounds of attorney-client privilege or work product protection. This will be completed on or before
[no later than **30 days after the court's Markman decision**]

A party opposing a claim of patent infringement who does not comply with these requirements shall not be permitted to rely on an opinion of counsel as part of a defense to willful infringement absent a stipulation of all parties or by order of the court, which shall be entered only upon a showing of good cause.

- Q. A party claiming patent infringement may serve “Final Infringement Contentions” that amend its Preliminary Infringement Contentions if that party in good faith believes that the court’s Claim Construction Ruling or the documents produced by the other part(ies) during the course of discovery so require. These shall be filed on or before _____ [within **30 days after the court's Markman decision**].
- R. Plaintiff shall serve (but not file with the court) on or before _____ [no later than **30 days after the court's Markman decision**] a statement of damages to be sought at trial, if any, and make a settlement demand. Defendants shall serve (but not file with the court) a response thereto within **30 days** after receipt of the demand.
- S. All parties shall file and serve their final witness and exhibit lists on or before _____ [no later than **30 days after the court's Markman decision**]. **These lists shall be updated (narrowed) every 30 days until trial witness lists are filed.** The final witness lists shall include a brief description of each witness’ anticipated testimony and certification by counsel that each witness has either been deposed in this action or interviewed by counsel.
- T. On or before _____ [no later than **60 days after the court's Markman decision**] each party opposing a claim of patent infringement may serve “Final Invalidity Contentions” without leave of court that amend its “Preliminary Invalidity Contentions” if: (i) a party claiming patent infringement has served “Final Infringement Contentions,” or (ii) the party opposing a claim of patent infringement believes in good faith that the court’s Claim Construction Ruling so requires.
- U. Amendment or modification of the Preliminary or Final Infringement Contentions or the Preliminary or Final Invalidity Contentions, other than as expressly permitted herein, may be made only by order of the court, which shall be entered only upon a showing of good cause.

- V. On or about _____ [**120 days after the court's *Markman* decision**] all fact discovery shall be completed.
- W. On or before _____ [**150 days after the court's *Markman* decision**] the parties bearing the burden of proof on a particular issue shall disclose the name, address, and vita of each expert witness, and shall serve the report required by Fed. R. Civ. P. 26(a)(2)(B).
- X. On or before _____ [**180 days after the court's *Markman* decision**] the parties not bearing the burden of proof on a particular issue shall disclose the name, address, and vita of all expert witnesses, and shall serve the report required by Fed. R. Civ. P. 26(a)(2)(B).
- Y. All dispositive motions shall be filed on or before _____ [**210 days after the court's *Markman* decision**] and shall be briefed pursuant to Local Rule 56.1.
- Z. All expert discovery shall be completed on or before _____ [**210 days after the court's *Markman* decision**].
- AA. Any party who believes that bifurcation at trial is appropriate with respect to any issue or claim shall file a motion to that effect as soon as practicable, but in no event later than _____ [**120 days prior to trial**]; responses shall be filed **within 15 days**; replies shall be filed **within 10 days**.
- BB. Any motions to exclude or limit expert testimony at trial (*Daubert* motions) shall be filed on or before _____ [**120 days prior to trial**]; responses shall be filed **within 15 days**; replies shall be filed **within 10 days**.
- CC. The court will schedule a case management conference approximately **320 days after the court's *Markman* decision**.

IV. Referral to Magistrate Judge

At this time, all parties do not consent to refer this matter to the Magistrate Judge pursuant to 28 U.S.C. § 636(b) and Federal Rule of Civil Procedure 73 for all further proceedings including trial.

V. Required Pre-Trial Preparation

- A. **SIXTY DAYS BEFORE THE FINAL PRETRIAL CONFERENCE**, the parties shall:
 1. File a list of witnesses who are expected to be called to testify at trial.

2. Number in sequential order all exhibits, including graphs, charts and the like, that will be used during the trial. Provide the court with a list of these exhibits, including a description of each exhibit and the identifying designation. Make the original exhibits available for inspection by opposing counsel. Stipulations as to the authenticity and admissibility of exhibits are encouraged to the greatest extent possible.
3. Submit all stipulations of facts in writing to the court. Stipulations are always encouraged so that at trial, counsel can concentrate on relevant contested facts.
4. A party who intends to offer any depositions into evidence during the party's case in chief shall prepare and file with the court and copy to all opposing parties either:
 - a. brief written summaries of the relevant facts in the depositions that will be offered. (Because such a summary will be used in lieu of the actual deposition testimony to eliminate time reading depositions in a question and answer format, this is strongly encouraged.); or
 - b. if a summary is inappropriate, a document which lists the portions of the deposition(s), including the specific page and line numbers, that will be read, or, in the event of a video-taped deposition, the portions of the deposition that will be played, designated specifically by counter-numbers.
5. Provide all other parties and the court with any trial briefs, along with all proposed jury instructions, *voir dire* questions, and areas of inquiry for *voir dire* (or, if the trial is to the court, with proposed findings of fact and conclusions of law).
6. File any motions in limine, which shall be briefed according to Local Rule 7.1.
7. Notify the court and opposing counsel of the anticipated use of any evidence presentation equipment.

B. **THIRTY DAYS BEFORE THE FINAL PRETRIAL CONFERENCE**, the parties shall:

1. Notify opposing counsel in writing of any objections to the proposed exhibits. If the parties desire a ruling on the objection prior to trial, a motion should be filed noting the objection and a description and

designation of the exhibit, the basis of the objection, and the legal authorities supporting the objection.

2. If a party has an objection to the deposition summary or to a designated portion of a deposition that will be offered at trial, or if a party intends to offer additional portions at trial in response to the opponent's designation, and the parties desire a ruling on the objection prior to trial, the party shall submit the objections and counter summaries or designations to the court in writing. Any objections shall be made in the same manner as for proposed exhibits. However, in the case of objections to video-taped depositions, the objections shall be brought to the court's immediate attention to allow adequate time for editing of the deposition prior to trial.
3. File any objections to proposed instructions and *voir dire* questions submitted by the opposing parties.
4. Notify the court and opposing counsel of requests for separation of witnesses at trial.

VI. Other Matters

The parties agree that: (A) drafts of expert reports will not be retained and produced; and (B) inquiry is not permitted into who, if anyone, other than the expert participated in the drafting of his/her report. The court will not entertain motions on these two issues.

In the event of a jury trial, at the final pretrial conference, the parties will inform the court whether the parties agree that the video "An Introduction to the Patent System," distributed by the Federal Judicial Center, should be shown to the jurors in connection with its preliminary jury instructions.

Exhibit numbering shall, to the extent possible, be maintained with a single and unique exhibit number throughout the entire case. A party first marking a document as an exhibit (whether with a pleading or declaration, for a deposition or trial, or otherwise) shall mark it, and the parties shall cooperatively track which documents are so marked, and shall thereafter use that exhibit numbering for all purposes. While it is preferable to have exhibits marked sequentially, the parties may also agree to ranges of exhibit numbers for their respective, initial marking. If the same document is marked with more than one exhibit number inadvertently, such multiple exhibit numbers shall remain. The parties are not to mark exhibits as letters, but may, and are encouraged to, mark related documents (such as duplicates with different bates numbers, or related versions of the same document) with numbers followed by letters (e.g. Exh. 7, Exh. 7-A, and Exh. 7-B).

DATED: March 11, 2011

JOINTLY SUBMITTED BY:

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and Barr Laboratories, Inc.*

If the required conference under LR 37.1 does not resolve discovery issues that may arise, **and if the dispute does not involve a claim of privilege**, the parties are ordered *jointly* to request a phone status conference before filing any motion to compel or for protective order. **If the dispute has arisen because a party has failed to timely respond to discovery, the party that served the discovery may proceed with a motion to compel without seeking a conference. Any contacts with the court to request a discovery conference must be made jointly by counsel, absent compelling circumstances.**

When filing a non-dispositive motion, the movant shall contact counsel for the opposing party and solicit opposing counsel's agreement to the motion. The movant shall indicate opposing counsel's consent or objection in the motion.

Upon approval, this Plan constitutes an Order of the Court. Failure to comply with an Order of the Court may result in sanctions for contempt, or as provided under Rule 16(f), to and including dismissal or default.

Approved and So Ordered.

03/22/2011
Date

Debra McVicker Lynch
Debra McVicker Lynch
United States Magistrate Judge
Southern District of Indiana